In The United States Patent And Trademark Office

Appl. No.:

09/842,466

Confirmation No.: 8005

Applicant(s): Filed:

Kokubo et al. 04/26/2001

Art Unit:

1616

Examiner:

H. Sheikh

Title:

SOLID PREPARATION COATED WITH A FILM COATING

LAYER AND FILM COATING AGENT

Docket No.:

035576/233803

Customer No.: 00826

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

APPELLANT'S REQUEST FOR REHEARING 37 CFR § 41.47

Pursuant to 37 CFR § 41.47, the Appellant hereby requests a rehearing. This request is timely filed within two months after the Decision on Appeal, dated April 12, 2010.

It is not believed that any fees are due for filing a rehearing request. However, if fees are due, any fee required therefore is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

Timothy J. Balts

Registration No. 51,429

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REQUEST FOR REHEARING UNDER 37 CFR 41.52

This Request for Rehearing is filed in response to the Decision on Appeal decided on April 12, 2010 the Decision on Appeal being in response to an Appeal Brief filed September 2, 2008, and the Reply Brief filed January 22, 2009. Appellants respectfully request the Board's reconsideration of the Decision on Appeal based on the statements below, which are limited to stating with particularity the points believed to have been misapprehended or overlooked by the Board as required by 37 CFR 41.52.

I. Summary of arguments on Appeal

Appellants appealed from the final rejections issued in the Office Action dated April 4, 2008. In both the Appeal Brief and Reply Brief, Appellants presented arguments that both of the cited references (the Berta and Hogan patents) failed to teach or suggest a medicament coated with a multi-colored continuous film coating layer. In the Final Office Action and the Examiner's Answer, the Examiner relied on Hogan (column 4, lines 32-44) for allegedly teaching a multi-colored tablet having a continuous coating. In the Decision on Appeal, the Board agreed with the Appellants that Berta does not disclose or suggest a medicament having a multicolored continuous film coating. With respect to Hogan, the Board agreed with the Examiner's interpretation that Hogan teaches a multi-colored continuous coating. Appellants

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disagree and assert that the Board erred as a matter of fact in finding that Hogan teaches a multicolored <u>and</u> continuous coating.

Appellants also presented arguments that neither of Berta nor Hogan teach or suggest a medicament coated with a multi-colored continuous film coating layer, and wherein the film coating layer includes a patter of two or more different colors, and in particular, where the pattern comprises a logo, barcode, or letters as recited in claims 18-20 and 44-47. In the Decision on Appeal, the Board stated that the dependent claims have not been argued separately and therefore fall with independent Claims 31 and 33. However, the claims were separately argued on pages 10 and 11 of Appellants' Appeal Brief dated September 2, 2008, and therefore the Board erred in not separately addressing the patentability of these claims.

II. Appellants remarks in response to Decision on Appeal.

A. Hogan does not teach a continuous coating

The issue on Request for Rehearing with respect to independent Claims 31 and 33 basically turns on whether the multi-colored coating in Hogan can be considered continuous. Appellants respectfully submit that it cannot for the same reasons the coating of Berta cannot be considered continuous and that the Board erred as a matter of fact and law in affirming the rejections based on Hogan. In particular, the Board erred by concluding that the coating of Hogan is continuous and multi-colored and also by not considering the teachings of Hogan as a whole.

As noted in Appellants' Appeal Brief Hogan describes a process for preparing a multi-colored tablet in which a <u>coating powder</u> is electrostatically applied to the tablet followed by exposing the coating to heat or electromagnetic radiation, such as infrared radiation, to cause the powder to melt and form a liquid. See column 4, lines 32 – 44. <u>Upon cooling</u>, the liquid forms a coating on the tablet's surface to which the powder particles have been applied. To produce a multi-colored tablet, Hogan describes partly coating the tablet with a first coating followed by supporting the coated tablet adjacent to the powder source and selectively applying an electromagnetic field to coat a second and uncoated portion of the tablet. See discussion on column 12, lines 30-44.

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In particular, Hogan teaches that to produce a multi-colored tablet, a first powder is applied and fused to partly coat the tablet, and that in a subsequent and second step, a second coating powder of a different colorant is electrostatically applied to the uncoated portions of the tablet, followed by exposure to heat or electromagnetic radiation as described previously to form a multi-colored tablet. The heat or electromagnetic radiation is applied so as to fuse particles of the second coating powder together and create a film coating on the other uncoated portion of the tablet. Thus it can be seen in Hogan that in order to produce a multi-colored tablet, a first coating is applied to half of the tablet followed by applying a second coating to the uncoated portion of the tablet. Notably, this is very similar to the first step in the two-dip process described in Berta, which the Board agreed did not produce a continuous coating.

As in Berta, the two-step process of Hogan to create a multi-colored tablet necessarily creates a coating that is not <u>continuous</u>. In particular, the two-step process (i.e., the separate steps of applying and fusing the powder particles of each portion of the tablet) of Hogan also comprises two distinct coatings that are separately applied and formed on the tablet. As such, Hogan teaches a multi-colored tablet having <u>two separate coatings</u> covering distinct portions of the tablet and does not have the presently claimed multi-colored and <u>continuous coating layer</u>.

The Examiner and Board rely on column 4, line 40 and column 7, line 61 – column 8, line 16 for the finding that Hogan teaches a continuous coating that is multi-colored. However, it is clear that these excerpts are not referring to the forming a <u>multi-colored and continuous</u> coating.

First, these excerpts are referring to the forming a continuous coating that is formed from a composite powder coating having two or more components. See column 2 line 21-column 4, line 44. It appears that the Examiner and Board erred in interpreting these two components as two distinct powders that are separately applied to form a continuous coating rather than a composite coating as described previously in Hogan. See columns 2-4 describing a composite powder having two components. As such, the Board erred in failing to consider the teaching of Hogan as a whole. Rather, a review of Hogan and the cited excerpts reveals that the cited teachings are directed to a continuous coating, but are not directed to a coating that is both

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<u>continuous and multi-colored.</u> As noted above, a multi-colored tablet is discussed beginning in columns 11 and 12.

The discussion on column 4 is referring to a continuous coating formed from the composite powder material, which is discussed in columns 2 and 3. Similarly, column 7 and 8 describe that this first component of the composite powder is able to form a continuous film. For example, column 7, line 61-63 states that the "first component ... is fusible to form a continuous coating..." and column 8, lines 13-16 states the first component may comprise polyethylene glycol which has good fusibility properties and, after treatment, can form a good continuous coat over the surface of the substrate." (Emphasis Added). Thus, it can be seen that the excerpts relied on by the Board actually teach that the first component is able to make a continuous film after fusing. Notably, these excerpts are silent with respect to the film being multi-colored. As noted above, Hogan teaches at column 12 applying two separate powders in distinct steps to create a multi-colored tablet. As such, Hogan teaches a multi-colored tablet having two separate coatings covering distinct halves of the tablet and does not have the presently claimed multi-colored continuous coating layer.

B. The Board Erred in failing to address the patentability of Claims 18-20 and 44-47

As argued in Appellants' Appeal Brief, Section D, neither Berta nor Hogan, describe a multi-colored continuous film coating having a pattern, logo, bar code or letters as part of the coating. As these claims were separately argued in Appellants' Appeal Brief, it was error for the Board to not address the patentability of these claims.

As noted, there is absolutely no teachings in either Berta or Hogan on how their respective teachings can be modified to produce a coating having a pattern, logo, bar code or letters. The Examiner completely fails to disclose how such a coating could be obtained by modifying the cited references. The Examiner glosses over this glaring deficiency by stating that the inclusion of logos, bar codes or letters as instantly claimed does not make the invention patentable since variations in designs or patterns in solid medicament forms is commonly and routinely practice in the pharmaceutical art. This statement completely fails to address or cite

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any prior art that teaches a solid preparation having <u>a continuous multi-colored coating layer in</u> which the coating layer includes logos, bar codes or letters as part of the coating. This element is completely missing from the cited art. The fact that it is known to include caplets/tablets with logos, bar codes, or letters does not disclose or suggest a <u>continuous coating layer having such as</u> part of the coating.

Furthermore, the tablet of Berta is dipped into two different baths to produce a multi-colored tablet. There is absolutely no teaching of how such a method could be used to produce a continuous coating with a pattern, such as a logo, bar code or letters in which the pattern is part of the coating. Accordingly, there are absolutely no teachings in either Berta or Hogan of a solid preparation having a continuous multi-colored coating layer in which the coating layer includes logos, bar codes or letters as part of the coating. Accordingly, the rejections of Claims 18-20 and 44-47 should be reversed for these additional reasons.

III. Conclusion

Accordingly, based on the points made above and the arguments previously presented in the Appeal Brief and Reply Brief, Appellants respectfully request that the rejections be reversed.

Respectfully submitted,

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